CLAIMS

1. A pharmaceutical composition for oral administration comprising a fixed dose combination of a first solid composition containing fenofibrate as the active substance and second solid composition containing an HMG-CoA reductase inhibitor as the active substance, wherein the first and the second pharmaceutical composition are present in separate entities in a single solid dosage form.

2. The pharmaceutical composition according to claim 1, wherein the first solid pharmaceutical composition is in the form of granulate, granules, grains, beads or pellets.

3. The pharmaceutical composition according to claim 1, wherein the second solid pharmaceutical composition is in the form of granulate, granules, grains, beads or pellets.

4. The pharmaceutical composition according to claim 3, wherein the granules, granulate, grains, beads or pellets are entero-coated.

5. The pharmaceutical composition according to claim 3, wherein the granules, granulate, grains, beads or pellets are coated with a protective coating.

6. The pharmaceutical composition according to claim 1 in the form of a capsule or a sachet.

7. The pharmaceutical composition according to claim 1 in the form of a tablet.

8. The pharmaceutical composition according to claim 7, wherein the first and second pharmaceutical compositions are present in the tablet in separate layers.

9. The pharmaceutical composition according to claim 8, wherein a layer comprising the first pharmaceutical composition is separated from a layer comprising the second pharmaceutical composition by an intermediate, inactive layer.

10. The pharmaceutical composition according to claim 1, wherein the HMG-CoA reductase inhibitor is a statin selected from the group consisting of atorvastatin, lovastatin, pravastatin, simvastatin, rosuvastatin, fluvastatin and pitavastatin.

11. The pharmaceutical composition according to claim 10, wherein the HMG-CoA reductase inhibitor is simvastatin.

12. The pharmaceutical composition according to claim 11 comprising a fixed dose combination selected from the group consisting of simvastatin 5 mg and fenofibrate 100 mg ; simvastatin 10 mg and fenofibrate 100 mg ; simvastatin 20 mg and fenofibrate 100 mg ; simvastatin 40 mg and fenofibrate 100 mg ; simvastatin 80 mg and fenofibrate 100 mg ; simvastatin 5 mg and fenofibrate 110 mg ; simvastatin 10 mg and fenofibrate 110 mg ; simvastatin 20 mg and fenofibrate 110 mg ; simvastatin 40 mg and fenofibrate 110 mg ; simvastatin 80 mg and fenofibrate 110 mg ; simvastatin 5 mg and fenofibrate 120 mg ; simvastatin 10 mg and fenofibrate 120 mg : simvastatin 20 mg and fenofibrate 120 mg ; simvastatin 40 mg and fenofibrate 120 mg ; and simvastatin 80 mg and fenofibrate 120 mg; simvastatin 5 mg and fenofibrate 130 mg ; simvastatin 10 mg and fenofibrate 130 mg : simvastatin 20 mg and fenofibrate 130 mg ; simvastatin 40 mg and fenofibrate 130 mg ; simvastatin 80 mg and fenofibrate 130 mg; ; simvastatin 5 mg and fenofibrate 145 mg ; simvastatin 10 mg and fenofibrate 145 mg : simvastatin 20 mg and fenofibrate 145 mg ; simvastatin 40 mg and fenofibrate 145 mg ; and simvastatin 80 mg and fenofibrate 145 mg.

13. The pharmaceutical composition according to claim 10, wherein the HMG-CoA reductase inhibitor is atorvastatin.

14. The pharmaceutical composition according to claim 13, wherein the atorvastatin is selected from the group consisting of crystalline atorvastatin calcium, amorphous atorvastatin calcium, crystalline atorvastatin magnesium, amorphous atorvastatin magnesium, a mixture of amorphous and crystalline atorvastatin calcium and a mixture of amorphous and crystalline atorvastatin magnesium.

15. The pharmaceutical composition according to claim 13, wherein the atorvastatin is crystalline atorvastatin magnesium.

16. The pharmaceutical composition according to claim 13 comprising a fixed dose combination selected from the group consisting of atorvastatin 5 mg and fenofibrate 100 mg; atorvastatin 10 mg and fenofibrate 100 mg; atorvastatin 20 mg and fenofibrate 100 mg;

atorvastatin 40 mg and fenofibrate 100 mg; atorvastatin 80 mg and fenofibrate 100 mg; atorvastatin 5 mg and fenofibrate 110 mg; atorvastatin 10 mg and fenofibrate 110 mg; atorvastatin 20 mg and fenofibrate 110 mg; atorvastatin 40 mg and fenofibrate 110 mg; atorvastatin 80 mg and fenofibrate 110 mg; atorvastatin 5 mg and fenofibrate 120 mg; atorvastatin 10 mg and fenofibrate 120 mg: atorvastatin 20 mg and fenofibrate 120 mg; atorvastatin 40 mg and fenofibrate 120 mg; and atorvastatin 80 mg and fenofibrate 120 mg; atorvastatin 5 mg and fenofibrate 130 mg; atorvastatin 10 mg and fenofibrate 130 mg: atorvastatin 20 mg and fenofibrate 130 mg; atorvastatin 40 mg and fenofibrate 130 mg; and atorvastatin 80 mg and fenofibrate 130 mg; atorvastatin 5 mg and fenofibrate 145 mg; atorvastatin 10 mg and fenofibrate 145 mg: atorvastatin 20 mg and fenofibrate 145 mg; atorvastatin 40 mg and fenofibrate 145 mg; and atorvastatin 80 mg and fenofibrate 145 mg.

17. The pharmaceutical composition according to claim 13 which further comprises a stabilizer capable of providing a microenvironment for atorvastatin having a pH of at least about 5.

18. The pharmaceutical composition according to claim 13 which further comprises a stabilizer capable of providing a microenvironment for atorvastatin having a pH of at least about 6.

19. The pharmaceutical composition according to claim 13 which further comprises a stabilizer selected from the group consisting of inorganic alkalizing compounds.

20. The pharmaceutical composition according to claim 19, wherein the stabilizer is selected from the group consisting of metal salts, alkaline earth metal salts, talc and bentonite.

21. The pharmaceutical composition according to claim 19, wherein the stabilizer is selected from the group consisting of calcium salts (calcium carbonate, calcium hydroxide, di calcium phosphate, tri calcium phosphate), magnesium salts (magnesium carbonate, magnesium hydroxide, magnesium silicate, magnesium aluminate, aluminum magnesium hydroxide), lithium salts (lithium hydroxide), potassium salts (potassium hydroxide) and sodium salts (sodium bicarbonate, sodium borate, sodium carbonate, sodium hydroxide).

22. The pharmaceutical composition according to claim 13 which further comprises a stabilizer selected from the group consisting of organic alkalizing compounds.

23. The pharmaceutical composition according to claim 22, wherein the stabilizer is selected from the group consisting of amines, amides and ammonium compounds.

24. The pharmaceutical composition according to claim 22, wherein the stabilizer is selected from the group consisting of ammonia, ammonium lactate, ammonium bicarbonate, ammonium hydroxide, ammonium phosphate dibasic, mono ethanolamine, di ethanolamine, tri ethanolamine, tri hydroxymethylaminomethane, ethylenediamine, N-methyl glucamide, 6N-methyl glucamine, meglucamine, L-lysine and 2-amino-2-(hydroxymethyl)-1,3-propanediol.

25. The pharmaceutical composition according to claim 17, wherein the stabilizer is 2-amino-2-(hydroxymethyl)-1,3-propanediol.

26. The pharmaceutical composition according to claim 1, wherein the second composition comprises atorvastatin and from about 0.01% w/w to about 5% w/w of 2-amino-2-(hydroxymethyl)-1,3-propanediol.

27. The pharmaceutical composition according to claim 1, wherein the first or the second composition further comprises pharmaceutically acceptable excipients.

28. The pharmaceutical composition according to claim 1, wherein the first composition comprises micronized crystalline fenofibrate.

29. The pharmaceutical composition according to claim 1, wherein the first composition comprises a solid solution of fenofibrate dissolved in a vehicle comprising polyethylene glycol (PEG).

30. The pharmaceutical composition according to claim 27, wherein the first composition comprises a solid solution of fenofibrate dissolved in a vehicle comprising polyethylene glycol 6000 (PEG 6000) and poloxamer 188.

31. The pharmaceutical composition according to claim 27, wherein the first composition comprises lactose as a carrier.

32. The pharmaceutical composition according to claim 27, wherein the first composition comprises magnesium stearate as a lubricant.

33. The pharmaceutical composition according to claim 1, wherein the second composition comprises simvastatin and lactose as a carrier.

34. The pharmaceutical composition according to claim 1, wherein the second composition comprises atorvastatin magnesium and mannitol as a carrier.

35. The pharmaceutical composition according to claim 27, wherein the second composition comprises magnesium stearate as a lubricant.

36. The pharmaceutical composition according to claim 27, wherein the second composition comprises starch as a disintegrant.

37. The pharmaceutical composition according to claim 27, wherein the second composition comprises one or more antioxidants selected from the group consisting of ascorbic acid, citric acid and butyl hydroxyl anisole.

38. The pharmaceutical composition according to claim 27, wherein the second composition comprises microcrystalline cellulose as a filler.

39. The pharmaceutical composition according to claim 1, wherein the single solid dosage form is a two-layer tablet prepared by compressing the first pharmaceutical composition in the form of granulate together with the second pharmaceutical composition in the form of granulate

40. The pharmaceutical composition according to claim 1, wherein the single solid dosage form is a two-layer tablet prepared by compressing the first pharmaceutical composition in the form of granulate together with the second pharmaceutical composition in the form of granulate having a protective coating.

41. The pharmaceutical composition according to claim 1, wherein the single solid dosage form is a two-layer tablet prepared by compressing the first pharmaceutical composition in the

form of granulate together with the second pharmaceutical composition in the form of entero-coated granulate.

42. The pharmaceutical composition according to claim 1 containing not more than 0.5% atorvastatin in lactone form after storage at 40°C and 75% relative humidity for 1 month.

43. The pharmaceutical composition according to claim 1 containing not more than 0.1% atorvastatin in lactone form after storage at 40°C and 75% relative humidity for 1 month.

44. The pharmaceutical composition according to claim 1 containing not more than 0.05% atorvastatin in lactone form after storage at 40°C and 75% relative humidity for 1 month.

45. The pharmaceutical composition according to claim 1 for the treatment of a subject suffering from atherosclerosis, hyperlipidemia, and/or hypercholesterolemia.

46. The pharmaceutical composition according to claim 43 for the treatment of a human subject.

47. A method for preparing a tablet comprising a first solid pharmaceutical composition containing fenofibrate as the active substance and second solid pharmaceutical composition containing an HMG-CoA reductase inhibitor as the active substance, the first and the second pharmaceutical composition being present in separate entities, which method comprises the steps of:

i) preparing the first solid pharmaceutical composition by dissolving fenofibrate in a vehicle and spraying the resulting liquid solution on a solid carrier in a controlled agglomeration process, optionally mixing the agglomerated particles with a lubricant, and mixing the agglomerated particles to form a granulate,

ii) preparing the second solid pharmaceutical composition by wet granulation, and

iii) compressing the first and second compositions into a multilayer tablet, the first and second compositions being present in separate layers.

48. A single solid dosage form comprising a pharmaceutical composition for oral administration comprising a fixed dose combination of a first solid composition containing fenofibrate as the active substance and second solid composition containing an HMG-CoA

reductase inhibitor as the active substance, wherein the first and the second pharmaceutical composition are present in separate entities.